Solent Healthcare

Serial Number:

Operative Date:

Review Date:

SERIOUS INCIDENTS REQUIRING INVESTIGATION (SIRI) Policy

Purpose of Policy:
The purpose of this policy is to describe the process for reporting, investigating and performance managing all Serious Incidents Requiring Investigation (SIRI). This applies to Solent Healthcare, the Provider arm of Southampton City PCT.

For action by:
All staff
It is recommended that Independent contractors adopt this policy.

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Responsibility for dissemination to new staff:
All service and departmental heads

Intranet and Website Upload

Intranet	Electronic Document Library Location:	• Policies and Procedures • Corporate Business & Operations
Website	Location in FOI Publication Scheme	Our Policies and Procedures
Keywords:	Incident, Serious Untoward Incident, SUI, Never event	

Amendments Summary:

Amend No	Issued	Page	Subject	Action date

Review Log
Include details of when the document was last reviewed:

Version Number	Review Date	Lead Name	Ratification Process	Notes

Routes of Consultation
Risk Management Team
NHSLA & Operational Policy Steering Group

Routes of Ratification
IGAP
Solent Healthcare Board
SCPCT Board

Solent Healthcare
Serious Incidents Requiring Investigation (SIRI) Policy

To be updated

APPENDICES

Serious Incidents Requiring Investigation Policy

1. POLICY STATEMENT

The systems-improvement approach to safety acknowledges that causes of incidents cannot simply be linked to the actions of individual people. The framework therefore uses a system-wide perspective for notification, management and learning from serious incidents. It supports openness, trust and continuous learning and service improvement. Where relevant, it highlights where engagement with relevant bodies for full investigation and identification of learning from a serious incident is needed.

The purpose of this policy is to:

- Provide a consistent definition of a serious incident that requires investigation;
- Clarify roles and responsibilities;
- Provide information on requirements and timescales;
- Draw together legal and regulatory requirements associated with the management of serious incidents and which form the basis of this framework;
- Provide an overarching framework developed from good practice, along with signposting tools and resources that support good practice;
- Provide guidelines to ensure that all incidents are reported to the relevant bodies to ensure full investigation (including independent investigations) and learning from the event.

This policy supports openness, trust, continuous learning and service improvement from serious incidents.

2. SCOPE

When a serious incident occurs it can have a devastating and far reaching effect. It may have an impact on those directly involved, patients, relatives, staff or visitors, and also on the reputation of the healthcare organisation, the service or the profession within which the incident occurred, and the wider NHS.

2.1 This policy applies to all directly and indirectly employed staff and other persons working within Solent Healthcare.

2.2 Solent Healthcare is committed to the principles of equality and diversity and will work to eliminate unlawful discrimination in all its forms. We will strive towards demonstrating fairness and equal opportunities for users of services, carers, the wider community and PCT staff.

3. DEFINITION OF SERIOUS INCIDENTS REQUIRING INVESTIGATION (SIRI) AND 'NEVER EVENTS'

A serious incident requiring investigation is defined as an **incident** that occurred in relation to **NHS-funded services and care** resulting in one of the following:

- **Unexpected** or **avoidable** death of one or more patients, staff, visitors or members of the public.

- **Serious harm** to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, **major surgical/medical** intervention, **permanent harm** or will shorten life expectancy or result in **prolonged pain or psychological harm** (this includes incidents graded under the NPSA definition of severe harm).
- A scenario that prevents or threatens to prevent a provider organisation's ability to continue to deliver healthcare services, for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment, or IT failure.
- Allegations of **abuse**.
- Adverse media coverage or public concern about the organisation or the wider NHS.
- One of the core set of 'Never Events' as updated on an annual basis and currently including:
  - Wrong-site surgery;
  - Retained instrument post-operation;
  - Wrong route administration of chemotherapy;
  - Misplaced nasogastric or orogastric tube not detected prior to use;
  - Inpatient suicide using non-collapsible rails;
  - Escape from within the secure perimeter of medium or high security mental health services by patients who are transferred prisoners;
  - In-hospital maternal death from post-partum haemorrhage after elective caesarean section;
  - Intravenous administration of mis-selected concentrated potassium chloride.

Supplementary terms

1. **Incident** – an event or circumstance that could have resulted, or did result, in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitors or members of the public[1].
2. **NHS-funded services and care** – healthcare that is partially or fully funded by the NHS, regardless of the location[2,3].
3. **Unexpected death** – where natural causes are not suspected[3]. Local organisations should investigate these to determine if the incident contributed to the unexpected death[2].
4. **Permanent harm** – directly related to the incident and not to the natural course of the patient's illness or underlying conditions, defined as permanent lessening of bodily functions, including sensory, motor, physiological or intellectual[3].
5. **Prolonged pain and/or prolonged psychological harm** – pain or harm that a service user has experienced, or is likely to experience, for a continuous period of 28 days[4].
6. **Severe harm** – a patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care[3].
7. **Major surgery** – a surgical operation within or upon the contents of the abdominal or pelvic, cranial or thoracic cavities or a procedure which, given the locality, condition of patient, level of difficulty, or length of time to perform, constitutes a hazard to life or function of an organ, or tissue (if an extensive orthopaedic procedure is involved, the surgery is considered 'major')[5].
8. **Abuse** – a violation of an individual's human and civil rights by any other person or persons. Abuse may consist of single or repeated acts. It may be physical, verbal

or psychological, it may be an act of neglect or an omission to act, or it may occur when a vulnerable person is persuaded to enter into a financial or sexual transaction to which he or she has not consented, or cannot consent. Abuse can occur in any relationship and may result in significant harm or exploitation of the person subjected to it.

This is defined in *No Secrets* for adults REF and in Care Quality Commission (CQC) guidance about compliance REF. *Working together to safeguard children* REF states that 'abuse and neglect are forms of maltreatment of a child. Somebody may abuse or neglect a child by 'inflicting harm' or by failing to act to prevent harm'.

3.1 When an Information Governance SIRI occurs staff will follow the Department of Health (2009) *Checklist for Reporting, Managing and Investigating Information Governance Serious Untoward Incidents* guidance, which can be found on the intranet in the Risk Management Folder.

The risk associated with Information Governance incidents will be measured using the table below:

0	1	2	3	4	5
No significant reflection on any individual or body Media interest very unlikely	Damage to an individual's reputation. Possible media interest, e.g. celebrity involved	Damage to a team's reputation. Some local media interest that may not go public	Damage to a services reputation/ Low key local media coverage.	Damage to an organisation's reputation/ Local media coverage.	Damage to NHS reputation/ National media coverage.
Minor breach of confidentiality. Only a single individual affected	Potentially serious breach. Less than 5 people affected or risk assessed as low, e.g. files were encrypted	Serious potential breach & risk assessed high e.g. unencrypted clinical records lost. Up to 20 people affected	Serious breach of confidentiality e.g. up to 100 people affected	Serious breach with either particular sensitivity e.g. sexual health details, or up to 1000 people affected	Serious breach with potential for ID theft or over 1000 people affected
From: Department of Health (2009) *Checklist for Reporting, Managing and Investigating Information Governance Serious Untoward Incidents* (page 9).					

Specialist advice regarding information governance issues can be sought from the Information Governance Team 023 80 725437.

3.2 If there is any doubt as to whether or not an incident should be classed as a SIRI, the Strategic Health Authority SIRI Lead should be contacted for advice.

4. ROLES AND RESPONSIBILITIES

4.1 The **Chief Operating Officer** has ultimate responsibility for all aspects of risk management, including the management of incidents and SIRI. This involves ensuring services are adequately resourced to comply fully with this policy.

4.2 The (Associate) Directors have responsibility to:

- ensure compliance with this policy
- ensure that all investigations are dealt with effectively and appropriately

4.3 Heads of Service have a responsibility to:

- be aware of, and comply with this policy
- provide support to all staff and patients involved in reporting of SIRI or potential SIRI (actual and near miss)
- monitor the quality and effectiveness of reporting and subsequent investigations by receiving and commenting on trend analysis and investigation reports

4.4 The Risk Management Team has a responsibility to:

- be aware of, and comply with this policy
- identify SIRI reported via incident forms and safeguarding alerts, as SIRI and upload them onto the Strategic Executive Information System (STEIS)
- play a key role in ensuring that as a provider organisation that we meet the performance requirements of the commissioning organisation
- produce SIRI reports showing trends
- discuss root causes and learning from these incidents at the Risk, Incidents, Complaints and Claims Group
- highlight any particular concerns / changes to practice, and the lessons learned, to relevant staff with the assistance of the Continuous Improvement Manager.

4.5 The Caldicott Guardian and Senior Information Risk Officer (SIRO) has responsibility for:

- reflecting patients' interests regarding the use of patient identifiable information
- ensuring patient identifiable information is shared in an appropriate and secure manner
- fostering a culture for protecting and using data
- providing a focal point for managing information risks and incidents

4.6 Heads of Service/Departmental Managers have a responsibility to:

- be aware of, and comply with, this policy
- investigate all reported SIRIs and inform the Risk Management Team of the outcome
- be aware of all SIRIs reported in their team/department
- raise any concerns regarding SIRI with the relevant Service Manager
- ensure that all incident reports are completed with all relevant details and without delay and within 48 hours of incident occurring: in accordance with the Solent Healthcare Reporting of Adverse Incidents Policy
- review the relevant risk assessments following a SIRI
- inform the Risk Management Team if the SIRI results in staff absence from work (even if this does not happen immediately after the incident) or any changes to staff duties
- inform the Risk Management Team of any changes to action plans
- consider and, where appropriate, implement the Solent Healthcare *Being Open Policy* when reporting SIRI
- With the Patient Experience and engagement team, provide support to all staff and patients involved in an incident

4.7 Employees have a responsibility to:

- be aware of, and comply with, this policy
- consider and, when appropriate, implement the Solent Healthcare 'Being Open' Policy
- give details of actions on the incident reporting form
- report any risks that could warrant further investigation
- be fully open and co-operative with the SIRI reporting and investigation process

5. Process for communicating SIRI

5.1 All Solent Healthcare staff are expected to follow the Reporting of Adverse Incidents Policy which interlinks with this policy.

5.2 Solent Healthcare expects any Independent Contractors to have in place robust procedures for informing the organisation, via either the Executive Team, Heads of Service or designated link with the Contracting team.

5.3 As with all incidents, the main priority is to ensure the safety of those involved and those who may be affected as a result of the incident.

5.4 As soon as the SIRI has occurred, without delay and within 24 hours, the service manager (or person in-charge at the time) must be informed.

5.5 As soon as Solent Healthcare managers are aware that a SIRI has occurred, they should report it to:

Responsible (Associate) Director
Director of Clinical Excellence and Delivery
Associate Director of Clinical Excellence and Quality
Risk Manager and/or Head of Risk Management

or

If out-of-hours or if the Responsible (Associate) Director, Risk Manager, Director of Clinical Excellence and Delivery, Associate Director of Clinical Excellence and Quality are unavailable, the On-call Director

5.6 The report of a SIRI may be from a Service or Care Delivery Unit or from another source such as the Patient Experience Service Team, Safeguarding Team or Information Governance Team. The SIRI may also be identified by trend analysis or by recommendation by the Commissioning body.

5.7 The Risk Management Team (or the on-call Director) who has been informed of the SIRI will immediately (or as soon as practicable) undertake the following process:

- Ensure that immediate steps have been taken to ensure patient safety and to protect the site of the incident where appropriate.

- If the incident is considered to be a SIRI, the Risk Manager/Head of Risk Management or designate will inform South Central Strategic Health Authority of the incident by completing the relevant form on STEIS.

- The Commissioning body will be notified that a new SIRI has been submitted to STEIS.

- All SIRIs involving patients must be reported to the National Patient Safety Agency. Depending on the source of the incident, this report might have been completed by another organisation, in which case, it does not need to be re-reported.

- Ensure the recording and update of all serious incidents on the local risk management system (LRMS).

5.8 In some cases, the Risk Management Team may be informed about a SIRI from one of its services or externally e.g. when agreement has not been reached regarding the origin of the SIRI, such as in the case of a patient being admitted to one of Solent Healthcare's services with a Grade 4 pressure ulcer. If it is still unclear following initial investigation (no longer than 72hrs, three working days), the Commissioning Risk Management Team will report this as an SIRI until a full investigation determines the source of the SIRI.

6. Management/Investigation of a SIRI

The circumstances surrounding each incident vary in terms of levels of harm and numbers of people involved, risk exposure, financial loss, media interest and the need to involve other reporting stakeholders; therefore, the response to each incident should be proportionate to the scale, scope and complexity of each incident.

6.1 Identification and response

- In all instances, the first priority is to ensure the needs of individuals affected by the incident are attended to, including any urgent clinical care which may reduce the harmful impact.
- A safe environment should be re-established, all equipment or medication retained and isolated, and relevant documentation copied and secured to preserve evidence and facilitate investigation and learning. If there is a suggestion that a criminal offence has been committed, Solent Healthcare must contact the police.
- Early consideration must be given to the provision of information and support to patients, relatives and carers and staff involved in the incident, including information regarding support systems which are available to patients, relatives, visitors or contractors following guidance provided in the Solent Healthcare Being open policy.
- The needs and involvement of staff in the incident should also be considered.
- If the incident is potentially a child safeguarding or adult safeguarding concern, organisations will have established and robust local processes in place and a safeguarding alert must be raised. It is also important to identify where other agencies need to be brought into the management of a serious incident when required (see Appendix 1 and the appropriate Safeguarding Policy for guidance).

6.2 Strategy meeting

On receipt of notification of a SIRI the Clinical Risk Manager will make arrangements to convene a Strategy Meeting. This will take place between 48 and 72 hours (up to three working days) after notification of the incident has been received.

Attendees at the Strategy Meeting will include the Responsible Associate Director, Service Lead or Head of Business Unit where the incident occurred, an individual most able to describe the incident, the Head of Risk Management, the Associate Director for Clinical Excellence and Quality (or the Head of Quality), the Clinical Risk Manager and/or Secretary to the meeting.

Depending on the type of incident and how it was reported, other attendees may also be invited as follows: Information Governance, Human Resources, Safeguarding, Patient Experience Service Team.

The Strategy Meeting is charged with considering patient and staff safety elements of the incident – what has already been done and what needs to be done. If appropriate, prior to the meeting the Clinical Risk Manager would have arranged for a notes review, preparation of a chronology and the answering of any specific questions. This information will be available at the meeting.

A standard template is used to record the discussion and decisions from the Strategy Meeting. Please see Appendix 2. This template includes all information about the incident, the date it was reported, the date reported on STEIS and the STEIS reference.

Using the NPSA and Strategic Health Authority guidance, the meeting will agree whether the incident is:

- A SIRI requiring investigation and delivery of a report within 45 working days;
- A SIRI requiring investigation and delivery of a report within 6 months;
- A high risk incident requiring investigation and management;
- An incident requiring local investigation and management; or
- Should be passed to another agency/organisation.

The meeting will identify the Investigating Officer, the Specialist Officer and give a commissioning brief for the investigation detailing any specific questions that need to be answered. The meeting will also determine any additions to the core circulation list for the SIRI Alert and will determine the date for receipt of the draft report (period mid-point) and the date for the submission to the SIRI Panel. If the SIRI Panel dates will not allow for a high quality report to be produced within the timeframe, the Strategy Meeting will acknowledge this and require that the Commissioners be contacted by the Clinical Risk Manager to agree a more appropriate submission date.

If the incident is decided by the Strategy Meeting to be a high risk incident requiring investigation but does not fulfil the SIRI criteria, it will be graded and logged on STEIS as a Level 0 incident. Incident gradings are described in Appendix 3. The Clinical Risk Manager will liaise with the appropriate Service Manager or Business Unit Manager to ensure this decision is fed back and that the investigation is programmed.

The SIRI Alert email will be sent, following the meeting, to all Solent Healthcare Directors, Associate Directors, Communications Team and others on the agreed circulation list to keep them informed. A template for the SIRI Alert email is attached at Appendix 4.

6.3 Draft report

The draft Root Cause Analysis Investigation Report (SIRI Report) will be due by the mid-point of the investigation period. The Clinical Risk Manager will maintain contact with the Investigation Officer during the investigation. The draft report will take a standard format as agreed with Commissioners. The report format is attached at Appendix 5.

The draft SIRI Report will be submitted to the Clinical Risk Manager and the Responsible Associate Director. In discussion with the Investigating Officer the draft report will be examined against the Commissioning Brief to ensure that all key questions have been answered. The recommendations of the report will be considered and the Responsible Associate Director will draw up an action plan to address and implement improvements in response to the recommendations.

The SIRI Report and action plan will then be submitted to the agreed SIRI Panel meeting for consideration.

6.4 SIRI Panel

The SIRI Panel will have standard membership (including a Non-Executive Director) and will meet on a monthly basis. Terms of Reference and membership of the Panel is attached at Appendix 6. The Panel will consider the final SIRI Report, the recommendations and the actions to address these. They will also consider and advise on monitoring arrangements to ensure firstly that actions are completed and secondly, that actions had the desired effect changing practice and processes to prevent future reoccurrence of the incident without introducing new and potentially unmitigated risk issues.

The SIRI Panel is able to comment where they believe further investigation is needed whether this results in an amendment to the SIRI Report or an additional piece of risk management work outside the remit of the report.

The SIRI Panel will formally sign-off the SIRI Report for the organisation and agree to submit the report to Commissioners. In exceptional cases two members from the Director of Quality & Clinical Services, Medical Director and Associate Director of Clinical Excellence and Quality may together sign-off the report for the organisation. The sign-off will be documented on the bottom of the SIRI Report. An overview of the report and the decision made will still need to be presented to the SIRI Panel at the next available meeting. Once the report has been signed off by the organisation and submitted to Commissioners the 'clock' will stop. The Commissioners will close the SIRI on STEIS once the report has been accepted and a closure confirmation alert will be issued by the Clinical Risk Manager (Appendix 7).

The SIRI Panel will, on a monthly basis also receive a list of all new SIRI and a status report on all SIRI. This will include details of submissions and responses from Commissioners and closure on STEIS. With this overview, the SIRI Panel will be able to comment on the overall performance of the system and any trends in SIRI and will be able to report to IGAP. The SIRI Panel report will also be used to provide assurance to Commissioners on the Provider Contract on a quarterly basis.

7. Administration and learning

The Clinical Risk Manager and Corporate Risk Manager will ensure that documentation is held for each stage of the process. SIRI report findings will be discussed at the Risk, Incidents, Complaints and Claims Group on a monthly basis.

8. Training

8.1 Risk Management Training is incorporated in the following training sessions:

- Corporate Induction for all new staff
- Programme for Health and Safety Representative

8.2 The Risk Management Team also provides ongoing ad hoc training on request.

8.3 Those members of staff (Band 8a and above) who are required to undertake Investigations of SIRI, High Risk incidents or incidents that fall under the safe guarding umbrella will receive specific training for this role. This will include level 3 safe guarding training as detailed in the *Safeguarding Vulnerable Adults* policy. Detailed Root Cause Analysis Training provided by the risk team or external agency as required, and training provided by the Human Resources team in investigating potential poor practice and the disciplinary procedure.

8.4 To ensure the successful implementation and maintenance of the Risk Management Strategy and Policies, Board Members and all staff will be appropriately trained and skilled in carrying out risk assessment. The ongoing training programme will be developed further, including staff briefings, induction programmes and workshops.

9. Monitoring and Review

9.1 The policy may be reviewed at any time, at the request of staff side or management, but nevertheless, it will be reviewed automatically 6 months after it is agreed, and thereafter on a three yearly basis.

10. Related Policies

- Incident, Complaints/Concerns investigation, analysis and Organisational Learning Policy
- Adverse incident reporting Policy
- Risk Management Strategy
- Health & Safety Policy
- Being Open Policy
- Complaints Policy
- Safeguarding Adults Policy
- Safeguarding Children Policy

11. Equality & Diversity and Mental Capacity Act

11.1 An equality Impact Assessment form relating to this policy has been completed and was submitted with the policy during the ratification process, please see Appendix 8.

12. References

National Patient Safety Agency (2010) **National Framework for Reporting and Learning from Serious Incidents requiring Investigation**

NHS South Central (May 2010) **South Central Strategic Health Authority Guidance For Serious Incident Process**

Department of Health (2009) **Checklist for Reporting, Managing and Investigating Information Governance Serious Untoward Incidents** London: Department of Health

NHS South Central Strategic Health Authority (2009) **Checklist for Reporting, managing and Investigating Information Governance Serious Untoward Incidents** Newbury: NHS South Central Strategic Health Authority

National Patient Safety Agency (2009) **Never Events Framework 2009/10 - Process and Action for PCTs 2009/10** London: National Patient Safety Agency

Appendix 1

www.nrls.npsa.nhs.uk/patientsafetydirect - will need to write summary from this document – but unable to download at present

Appendix 2 – Strategy Meeting Template

Strategy meeting – SIRI no:
Incident No:
Date:
Location:

The contents of this meeting are to be treated as confidential and not shared with anyone outside of this forum unless on a need to know basis
Agreement to adhere to confidentiality statement indicated by all attendees – Chair's Signature: _____

The purpose of this meeting is to examine the collated evidence so far and make shared decisions relating to the process of management of this incident and:

- Agree the level of investigation required, based on the grading of the incident and the information provided to date
- Commission the investigation into this SIRI, which will include:
- Ensuring that any (patient) safety issues are addressed
- Identifying the scope and remit of the investigation
- Identifying roles and responsibilities regarding the investigation and production of the Root Cause Analysis Report
- Ensure that timelines for submission to commissioners are clear
- Identify individuals to be interviewed as part of the investigative process

Attendees:

Required		Optional	
Name	**Title**	**Name**	**Title**
	Responsible Director or Associate Director		Medical Director
	Head of Care Delivery Unit / Service Manager		HR representative
	Head of Risk / Clinical or Corporate Risk Manager		Head of Quality Improvement
	Associate Director of Quality / Head of Quality Improvement Clinical Excellence		

Communications Log – verbal brief given by Responsible Director or Risk Management Team					
Solent Communications Team	Date/Time Comments		Responsible (Associate) Director	Date/Time Comments	
Patient Experience and Engagement	Date/Time Comments		Chief Officer	Date/Time Comments	
Medical Director	Date/Time Comments		Director of Clinical Excellence and Delivery	Date/Time Comments	
Head of Service	Date/Time Comments		Associate Director of Clinical Excellence and Quality	Date/Time Comments	
Other :	Date/Time Comments		Risk Management Team	Date/Time Comments	

Patient Safety Issues – Summary *(Amend to reflect incident)*	
Issue	Action

Family /Carer/ Staff/External Contact:	Please detail:

Further Information Required			
Action	Date for completion	Update	By Whom

Action to be taken in regard of incident no:

Does this incident meet SIRI criteria to be raised by Solent Healthcare?	Yes/No	Grading of incident	0 / 1 / 2	Level of investigation required	Level 2 / Level 3	SIRI Category	
If this incident does not meet SIRI criteria and to be raised by Solent Healthcare, what action is to be taken?							

All information to be forwarded to Lead Investigator

Consideration for inclusion within RCA – Lead Investigator/RCA Author:

NB: Ensure draft report is fully anonimised before any circulation

Lead Investigator/RCA Author: _____ is requested to deliver an RCA report (as per SH template) to the point of recommendations (Action plan to be developed, agreed and added to report by Associate Director and monitor until completion)

With particular consideration to issues relating to:

-

Fact Finding:

Contacts

Diary Dates (assuming submission to STEIS same day)

	Level 2 (45 working days)	**Level 3** (6 months)
Mid point - Draft RCA should be delivered for circulation at this point		
Associate Director 'Sign off' required by:		
'Sign off' for submission by:		
Closure date :		
Presentation to Panel on :		

Circulation List – Please see guidance below

NOTE- consideration must be given to maintaining the integrity of the group and the confidentiality of the SUI investigation

	Name	Contact details

Responsible Director or Associate Director		Via global email ***All emails regarding this SIRI will be treated as confidential.*** ***Please use NHSmail for any messages containing personal, confidential or sensitive information using NHSmail address***
Head of Care Delivery Unit / Service Manager		
Lead Investigator/RCA Author		
Specialist		
Head of Risk / Clinical or Corporate Risk Manager		
Associate Director of Quality / Head of Quality Improvement Clinical Excellence		
Director of Clinical Excellence and Delivery		

Further information pertaining to this meeting:

Circulation List for SIRI Root Cause Analysis reports - Guidance		
Please select from the list below the appropriate contact to form the circulation group for each individual SIRI *– consideration must be given to maintaining the integrity of the group and the confidentiality of the SIRI investigation*		
Mandatory		
Responsible Director or Associate Director	Relevant to service incident occurred in	
Head of Care Delivery Unit / Service Manager	Relevant to service incident occurred in	Ref to SIRI Alert email
Lead Investigator/RCA Author	This is the person responsible for investigation of the incident and author of the Root Cause Analysis Report	Ref to SIRI Alert email
Specialist	This is the person identified to provide any 'specialist' knowledge pertinent to the investigation, professional advice and guide in aspects of the investigation	Ref to SIRI Alert email
Associate Director of Quality and Clinical Excellence		All SIRI
Head of Quality Improvement		All SIRI
Head of Risk		All SIRI
Clinical or Corporate Risk Manager		All SIRI
Include as appropriate		
Director of Quality and Clinical Services	If the SIRI has a professional (Clinical) focus or issue within it	
Human Resources	If the SIRI has a employment focus or issue within it	
Infection Prevention & Control	If the SIRI has an Infection control focus or issue within it	
Patient Experience Team	If the SIRI has an Patient Experience focus/issue within it or may give rise to a complaint	
Adult Safeguarding Lead	If the SIRI has a Adult Safeguarding focus or issue within it	
Child Protection (Safeguarding Children Lead)	If the SIRI has a Child Protection focus or issue within it	
Medicine's Management Lead/ Accountable Officer	If the SIRI has any Medicine's Management focus or issue within it	
Medical Director	If the SIRI has a Medical Practitioner focus/issue within it	
Information Governance/Calidcott Guardian/SIRO	If the SIRI has a Information Governance focus/issue within it	
External Agencies/Joint Agency RCA investigations		
Any External agencies	Should have an RCA report circulated **only following** internal circulation, but **prior** to the report being 'signed off' for submission for closure	
Business Support (Administration)		
Business Support Administration		

Appendix 3 – Grading of serious incidents

Grade 0: Action required
Notification only it is unclear if a serious incident has occurred.
The provider organisation must update the PCT/SHA with further information within three working days of a grade 0 incident being notified.
If within three working days it is found not to be a serious incident, it can be downgraded with the agreement of the accountable SHA/PCT.
If a serious incident has occurred it will be re-graded as a grade 1 or 2

Grade 1: Action required Commissioning PCTs will monitor the case and report findings, recommendations and associated action plans to the SHA. SHA will monitor progress on a quarterly basis with PCT unless earlier discussion is required or the serious incident is re-graded. **Comprehensive investigation Root Cause Analysis (RCA) required (level 2 Investigation)** **See Appendix C**	**Monitoring required** **Local monitoring** • The PCT and/or SHA will close the incident when it is satisfied the investigation, recommendations and action plan are satisfactory, and local monitoring arrangements are in place and working efficiently. • Publish incident details within Annual Reports **Timescales:** up to **45 working days/nine weeks** from the date the incident is notified to the PCT/SHA.	**Examples of cases** • Mental Health – deaths in the community* • Healthcare associated infection (HCAI) outbreaks • Avoidable/unexplained death • Mental health – attempted suicides as inpatients* • Ambulance services missing target for arrival resulting in death/severe harm to patient • Data loss and information security (DH Criteria level 2, see Information Resource) • Grade 3 pressure ulcer develops • Poor discharge planning causes harm to patient **See Information Resource Tool** www.nrls.npsa.nhs.uk/patientsafetydirect
Grade 2: Action required Case will be monitored by the SHA/PCT/local authority in conjunction with the provider organisation. The SHA will review findings, recommendations and associated action plans. For Never Events, the commissioning PCT will be obliged to monitor overall numbers and actions and report these in its annual reporting arrangements. **Comprehensive investigation (RCA level 2 investigation)** (as above) **or independent investigation (RCA level 3 investigation)** **See Appendix C**	**Monitoring required** **SHA/PCT monitoring** • Incidents leading to an independent investigation or inquiry or those considered high risk will continue to be monitored by the SHA/PCT or Local Authority until evidence is provided that each action point has been implemented. Incidents involving adult or child abuse are referred to local safeguarding arrangements. • Publish quarterly reports. **Timescales:** for independent investigations allow up to **26 weeks/six months** for completion of investigation. Extensions can be granted on an individual case-by-case basis by the SHA/PCT.	**Examples of cases** • Maternal deaths. • Inpatient suicides (including following absconsion)*. • Child protection. • Data loss and information security (DH Criteria level 3-5). • Never Events. • Accusation of physical misconduct or harm is made. • Homicides following recent contact with mental health services*. See Information Resource Tool * Mental Health incidents should refer to DH guidance: Independent investigation of adverse events in mental health services[14]

Grading of incidents supports a proportionate and appropriate response on a case-by-case basis. Timescales and levels of investigation reflect the scale, scope and complexity of each incident and are consistent with the triggers and levels of RCA investigation published by the NPSA .

Appendix 4 – SIRI Alert Email Template

SIRI (Serious Incident Requiring Investigation) Alert – For your information

(SIRI is the updated name for SUI)

SIRI ref Number	Type/ Category	SIRI Grade	Level of Investigation	Date Notified - STEIS

Lead Investigator	Specialist	Service	Head of Service

Reminder due (Mid point)	Closure deadline

Brief details of incident at the time of reporting :	

- Proposed RCA Meeting (Chair to be agreed) –
- If you have any queries or require further information please do not hesitate to contact the Risk Manager.
- **Please note** - All communication regarding this SIRI will identified by the SIRI reference number.
- Please note - the **mid point** milestone and the **closure** deadline if you are the Lead investigator or Head of Service

Everything contained within this email is to be treated as confidential and not shared to anyone unless on a need to know basis

Core Circulation List			
Chief Officer	Business Director/Deputy Chief Officer/SIRO	Director of Clinical Excellence and Delivery/ Caldicott Guardian	Head of Communications
Director of Human Resources	Associate Director of Clinical Excellence and Quality	Head of Patient Experience and Engagement	Medical Director
Director of Finance	Associate Director Adult Services	Head of Risk/Risk Managers	Head of Quality
Associate Director Primary Care and Specialist Services	Associate Director Child and Family services	Associate Director Mental Health Services	
Additional Circulation			
Specialist – Identified at Strategy Meeting	Relevant Head of Service– Identified at Strategy Meeting	The Lead investigator– Identified at Strategy Meeting	

Appendix 5 – Root Cause Analysis Report Template
and link to guidance documents

Solent Healthcare

Root Cause Analysis Investigation Report

SIRI Ref: ****/****

Adverse Incident Report no: ******

SIRI Category:

Business Unit:

Service:

Author:

Date: Month/Year

National Patient Safety Agency

RCA Investigation Report Template - Guidance

The following headings are designed to improve the recording of information currently considered good practice for investigation reports. These headings will be evaluated over time to confirm or challenge that understanding.

PLEASE READ - Instruction for use of this RCA Report Template

1. **Determine the level of investigation to be undertaken**
   Refer to the NPSA's 'Three Levels of investigation' (Level 1 = Concise; Level 2 = Comprehensive; Level 3 = Independent), to the NPSA's 'Triggers for Investigation', and to your own organisational policy and terms of reference.
2. **Delete all ROWS not required for the level of investigation being undertaken**
   The investigation level numbers in the middle column provide a guide to which rows are needed for which level of investigation. (i.e. for a Level 1 - Concise investigation you only need rows which have the number 1 in the 'Level' column)
3. **Write your investigation report in the right hand column**
   - Delete examples (in green), and refer to summary guidance in the left hand column as you go. For detailed guidance refer to the NPSA's 'Guide to RCA investigation report writing'.
   - If an investigation produces no information against a heading, add an explanation on why this is the case.
   - If issues arise which require a new heading this can be added as a new row
4. **On completion, delete the guidance to produce your final report**
   - Delete all guidance both here and in the template below (i.e. all green and red type, all green coloured rows and all green coloured columns)
   - Realign the remaining table containing your own report, so that it fits the whole page.
   - Save the document with the chosen file name for each individual investigation report.

Quick reference guide	Level	Type your investigation report in this column
Cover page • Organisation name and / or logo	2 + 3	

- Title or *Brief* outline of incident
- Incident date
- Incident number
- Author(s)
- Report date
- Page numbers
- Document version
- Computer File Path

Contents page 2 + 3

CONTENTS

Executive summary 2 + 3

A one page summary of the main report presented succinctly under the following headings:- 2 + 3

EXECUTIVE SUMMARY

Brief Incident description 2 + 3

- **Incident date:** 2 + 3
- **Incident type:** 2 + 3
- **Healthcare specialty:** 2 + 3
- **Actual effect on patient and/or service:** 2 + 3
- **Actual severity of the incident:** 2 + 3

Level of investigation conducted 2 + 3

Involvement and support of the patient and/or relatives 2 + 3

Detection of Incident 2 + 3

Care and Service Delivery Problems 2 + 3

Contributory Factors 2 + 3

Root Causes 2 + 3

Lessons Learned 2 + 3

Recommendations 2 + 3

Arrangements for Sharing Learning 2 + 3

Main Report 1, 2 +3

MAIN REPORT

Incident description and consequences 1, 2 +3

- Concise incident description

Incident description and consequences

Example only (please delete and add your own findings)
A lady with asthma sustained brain damage following IV administration

of a drug to which she was known to be allergic.

- Incident date 1, 2 +3
- Incident type 1, 2 +3
- Healthcare speciality involved 1, 2 +3
- Actual effect on patient and / or service 1, 2 +3
- Actual severity of incident 1, 2 +3

Incident date:
Incident type:
Specialty:
Effect on patient:
Severity level:

Pre-investigation risk assessment 2 + 3

Assess the realistic likelihood and severity of recurrence, using your organisation's Risk Matrix

Pre-investigation risk assessment

A Potential Severity (1-5)	B Likelihood of recurrence at that severity (1-5)	C Risk Rating (C = A x B)

Background and context to the incident 2 + 3

A brief description of the service type, service size, clinical team, care type, treatment provided etc.

Background and context

Terms of reference - Outline :- 2 + 3

- Specific problems to be addressed
- Who commissioned the report
- Investigation lead and team
- Aims, Objectives and Outputs (see examples opposite)
- Scope, boundaries and collaborations
- Administration arrangements (accountability, resources, monitoring)
- Timescales

Terms of reference

Example only (please amend to build your own aims)
To establish the facts i.e.:- **what** happened (the *effect*), to **whom**, **when**, **where**, **how** and **why** (*root causes*)
To establish whether failings occurred in care or treatment
To look for improvements rather than to apportion blame
To establish how recurrence may be reduced or eliminated
To formulate *recommendations and an action plan*
To provide a *report* as a record of the investigation process
To provide a means of *sharing learning* from the incident

Investigation team 2 + 3

Names, Roles, Qualifications, Dept.'s

The investigation team

Scope and level of investigation 1, 2 +3

- State level of investigation (NPSA -1.Concise; 2.Compre.; 3.Independent)
- Describe the start and end points
- List services & orgs involved

NB: for Level 3 'Independent' Investigations 'scope' could be included under Terms of Reference

Scope and level of investigation

Investigation type (i.e. Single / Aggregation / Multi-incident)**, process, and methods used** 2 + 3

- Gathering information e.g. *Interviews*
- Incident Mapping e.g. *Tabular timeline*
- Identifying Care and service delivery problems e.g. *Change analysis*
- Identifying contributory factors & root causes e.g. *Fishbones*
- Generating solutions e.g. *Barrier analysis*

Investigation type, process and methods used

Involvement and support of patient and relatives 1, 2 +3

e.g. Meetings to discuss questions the patient anticipates the investigation will address and to hear their recollection of

Involvement and support of patient and relatives

events (anonymised in line with the patient/relative wishes).
e.g. Family liaison person appointed, information given on sources of independent support.

Involvement and support provided for staff involved 2 + 3
Refer (anonymously) to involvement of staff in the investigation, and to formal & informal support provided to those involved and not involved in the incident.

Involvement and support provided for staff involved

Information and evidence gathered 2 + 3
A summary list of relevant local and national policy / guidance in place at the time of the incident, and any other data sources used:-
(Include:-Title and date of Guidance, Policies, Medical records, interview records, training schedules, staff rotas, equipment, etc)

Information and evidence gathered

Example only (please delete and add your own findings)
Interviews with the four staff on duty - 01.02.08
Interviews with patient relatives - 05.02.08
A visit to the location of the incident -14.02.08
The patient's clinical records

Chronology of events 1, 2 +3
For complex cases any summary timeline included in the report should be a summary

Chronology of events

See table below

Detection of incident 1, 2 +3
Note at which point in the patients treatment the error was identified. i.e.

- At risk assessment of new/changed service
- At pre-treatment patient assessment
- Error recognition pre-care/treatment
- Error recognition post-care/treatment
- By Machine/System/Environ. change/Alarm
- By a Count/Audit/Query/Review
- By Change in patient's condition

Detection of incident

Select from the list on the left

Add additional information

Notable practice 2 + 3
Points in the incident or investigation process where care and/or practice had an important positive impact and may provide valuable learning opportunities.
(e.g. Exemplar practice, involvement of the patient, staff openness etc)

Notable practice

Example only (please delete and add your own findings)
Actions taken to inform the patient and relatives of the error in an open and honest way, and to subsequently involve them in the RCA process was valued by all and greatly enhanced the investigation.

Care and service delivery problems 1, 2 +3
A themed list of the *key* problem points. (Where many problems have been identified the *full* list should be included in the appendix)

Care and service delivery problems

Example only (please delete and add your own findings)
Nurses on the short stay ward routinely failed to complete the section in the patient notes to highlight the existence of known allergies

Contributory factors 1, 2 +3
A list of significant contributory factors (where many contributory factors are identified a full list or 'fishbone diagrams' should be included in the appendix)

Contributory factors

Example only (please delete and add your own findings)
Over years numerous assessments for nutrition, pressure ulcers, falls risk etc. had been added, causing short stay wards to see the completion of all documentation as impossible.

Root causes (numbered) 1, 2 +3
These are the most fundamental underlying factors contributing to the incident that can be addressed. Root causes should be meaningful, (not sound bites such as communication failure) and there should be a clear link, by analysis, between root CAUSE and EFFECT on the patient.

Root causes

Example only (please delete and add your own findings)
1. When adding or updating patient assessments and care plans, risk assessment of the wider implications of their use should be conducted and acted upon to reduce the risk of impact on patient safety

Lessons learned (numbered) 1, 2 +3
Key safety and practice issues identified which may not have contributed to this incident but from which others can learn.

Recommendations (numbered and referenced) 1, 2 +3
Recommendations should be directly linked to root causes and lessons learned, They should be clear but not detailed (detail belongs in the action plan). It is generally agreed that key recommendations should be kept to a minimum where ever possible.

Arrangements for shared learning 1, 2 +3
Describe how learning has been or will be shared with staff and other organisations (e.g. through bulletins, PSAT/Regional offices, professional networks, NPSA, etc.)

Distribution list 2 + 3
Describe who (e.g. patients, relatives and staff involved) will be informed of the outcome of the investigation and how

Appendices 2 + 3
Include key explanatory documents. e.g. Tabular timeline, Cause + effect chart, Acknowledgements to patients, family, staff or experts etc.

Lessons learned

Example only (please delete and add your own findings)
1. A distinction should be made between essential and desirable documentation in clinical records

Recommendations

Example only (please delete and add your own findings)
1. Ensure allergy records and other priority assessment sheets are routinely filed prominently for ease of completion
2. Ensure essential assessment criteria are set as mandatory fields in new electronic record development

Arrangements for shared learning

Example only (please delete and add your own findings)
- Share findings with other departments caring for short stay patients and include them in piloting solutions
- Share findings with patient Safety Action Team to identify opportunities for sharing outside the organisation

Distribution list

Appendices

Author:

Job Title:

Date:

Date of SIRI Panel review	Attendees
RCA report reviewed and agreed as complete for submission to close	

Exceptional Review

RCA report reviewed and agreed as complete for submission to close (minimum two of below)

	Date	Sign
Director of Clinical Excellence and Delivery		
Associate Director of Clinical Excellence and Quality		
Medical Director		

Chronology (timeline) of events	
Date & Time	

Links to guidance documents

RCA toolkit www.nrls.npsa.nhs.uk/rca

Information resource to support the reporting of serious incidents
www.nrls.npsa.nhs.uk/patientsafetydirect

Additional narrative on what can be accessed, to be added.

Appendix 6 – SIRI Panel Terms of Reference

Solent Healthcare

Serious Incidents Requiring Investigation (SIRI) Panel
Terms of Reference

1. Purpose

The SIRI panel will be responsible for ensuring that each completed SIRI investigation adequately reflects the rigour and requirements from the SIRI Strategy meeting with a supporting action plan with time specific actions to be completed by specific leads. The panel will ensure that, following review of the report, its recommendation for closure is noted and the lessons learnt and organisational learning are appropriately transferred through the Quality Improvement Group (QIG) and Risks, Incidents, Complaints and Claims Group (RICC).
The SIRI panel is a formal sub committee of the Quality Improvement Group that reports to the Integrated Governance and Performance Committee (IGAP). The SIRI panel represents the decision making part within the overarching SIRI policy.

The SIRI Panel's main functions are:

- To receive a list of all new SIRI and a status report on all SIRI. (This will include details of submissions and responses from Commissioners and closure on the Strategic Executive Information System STEIS);
- To receive SIRI investigations reports within the agreed time frame reported through STEIS, in the correct NPSA format to reflect consistency, and with an accompanying time and service lead specific action plan;
- Ensure that the report reflects the commissioning brief and has determined contributory factors, root causes, and lessons learnt;
- Comment where the panel believes further investigation is needed either recommending amendments to the report or further specific risk management work outside the initial remit of the report;
- To formally recommend for closure after panel agreement that the investigation is complete.
- To confirm closure on STEIS once accepted by the Commissioners;
- Determine on the basis of individual SIRI received whether trend investigation or aggregated review is required;
- To provide assurance to Commissioners on the Quality Contract on a monthly basis;
- To provide assurance to the Board on a monthly basis.

2. Aims

The SIRI panel aim is:

- To ensure that serious incidents that require investigation are reported on STEIS and that a consistent and robust investigation process is in place to enable root causes to be established and lessons learnt to be disseminated and reviewed across Solent healthcare services.

3. Responsibilities & Scope of Authority

The investigation process will ensure that the panel can:

- Demonstrate the safeguarding of patients, property, the service's resources and its reputation;
- Understand why the event occurred;
- Ensure that steps are taken to reduce the likelihood of a similar event happening again;
- Sharing the learning.

The responsibilities and tasks of the SIRI panel include;

- **Director of Clinical Excellence and Delivery: (Chairperson)**
  1. Consistent rigour is applied to the review of all SIRI received by the panel.
- **All Associate Directors:**
  1. Ensure that all SIRI identified in their care delivery units are dealt with effectively and in line with the SIRI Policy providing service staff with support to provide the report within the required time frames;
  2. That commissioning briefs are provided in standard format (appendix xxx);
  3. They monitor the quality and effectiveness of the investigations;
  4. Assist with trend analysis;
  5. Review the RCA prior to submission to the panel and prepare the associated action plan.

- **Associate Director of Clinical Excellence and Quality**
  1. As above;
  2. Support the quoracy provision outlined under section 5;
  3. Shared responsibility with the Head of Risk Management for checking that any minor alterations have been made to reports and action plans following panel prior to submission to the commissioners.

- **Associate Director Child and Family Services**
  1. Responsible as part of the core decision making part of the panel in addition to the general responsibilities listed under 'all' Associate Directors.

- **Medical Director** (Vice Chair)
  1. Core member responsibility and specific decision responsibility to support quoracy provision outlined under section 5.

- **Non Executive Director**
  1 To provide an independent perspective to the investigation report and outcomes;
  2.To further demonstrate the Organisations commitment to patient safety and improvement.

- **Head of Risk Management**

1. Lead responsibility for the management of the SIRI process to ensure STEIS reporting time frames are achieved;
2. core panel member decision making responsibility;
3. Shared responsibility with the Associate Director of Clinical Excellence and Quality for checking any minor alterations have been made to reports and action plans following panel prior to submission to the commissioners.

- **Clinical Risk Manager**
    1. Ensure authors of reports are notified of the panel dates and agree times for presentation at the panel;
    2. Submits the completed SIRI report with action plan to commissioners following panel sign off;
    3. Ensures the entry on STEIS is completed when the commissioners have signed off the report;
    4. Will prepare the agenda for panel supported by the panel secretary.

- '***Quality Improvement Manager' (or equivalent)***
    1. To ensure that the Service Manager (recorded as lead for the action plan implementation) receives the action plan for follow through in the services Essential Standard group and reports to the QIM when the last action has been completed;
    2. Maintains a record of action plans and liaises with service leads to ensure the agreed time frames are met;
    3. Reports any failure to comply with actions recorded from SIRI investigations through RICC;
    4. To ensure that lessons learned from investigations are submitted to IGAP via the Quality Improvement group;
    5. To inform RICC when action plan completion dates have not been met.

Service Managers

- To ensure the SIRI action plan is submitted through the Essential Standards group, liaising with the Action plan Lead to ensure all actions are completed on time.

4. Membership

The SIRI Panel will have standard membership (including a Non-Executive Director) and will meet on a monthly basis.

- Director of Clinical Excellence and Delivery (Chairperson)
- Associate Director of Clinical Excellence and Quality
- Associate Director Child and Family Services
- Medical Director (Vice Chair)
- Non Executive Director
- Head of Risk Management

Associate Membership:

- Associate Director of Mental Health Services
- Associate Director of Care and Specialist Services
- Associate Director Adult Services
- Clinical Risk Manager
- Corporate Risk Manager
- Consultant Nurse Safeguarding Children
- Consultant Practitioner Safeguarding Adults
- Chief Pharmacist: Strategic and or Operational tbc
- Head of Information Governance
- Consultant Nurse /Head of Infection Control tbc
- 'Quality Improvement Manager' or equivalent

In attendance:

- Secretary to the panel

5. Quorum

No business shall be transacted at the meeting unless the following are present;

- Director of Clinical Excellence and Delivery (Chairperson)

or

- Medical Director (Vice Chair)

With a minimum of two of the following with additional membership from the associate members that reflects the type of SIRI's received.

- Non Executive Director
- Head of Risk Management
- Associate Director of Clinical Excellence and Quality
- Associate Director Child and Family Services

With the exception as identified by the Chairperson when the following will apply:

- The Director of Quality & Clinical Services, Medical Director and Associate Director of Clinical Excellence and Quality may together sign-off the report for the organisation. The report will still need to be presented to the SIRI Panel at the next available meeting.

6. Administration and Format of Meetings

6.1 Meeting will be held monthly. Minutes will be recorded by the panel secretary, reviewed by the chair and circulated within 7 working days of the panel to ensure follow up action can be undertaken within the required reporting framework.

6.2 Agenda setting will be determined by the Head of Risk Management with the Clinical Risk Manager. Administration will be provided by the secretary to the panel (long term tbc).

7. Reporting

In the event of Solent healthcare receiving a National enquiry summary report with implications for the organisation, the SIRI Panel will agree the actions that need to be undertaken.

7.1 Panel minutes to be presented to the confidential part of the Board meeting.

Version: [1]
Review Date: [date]
Next Review: [date]

Appendix 7 – Confirmation of Closure Email

SIRI (Serious Incident Requiring Investigation) – Closure Confirmed

(SIRI is the updated name for SUI)

SIRI ref Number	Type	Lead Investigator	Specialist	Service	Business Unit Head/Service Lead	Date closure confirmed

Brief details of the incident at the time of reporting :	

- Please note closure agreed of this SIRI
- If you would like a copy of the final report please contact the Risk Manager
- If you have any queries or require further information please do not hesitate to contact the Risk Manager.
- **Please note** – Any communication regarding this SIRI will identified by the SIRI reference number.

Core Circulation List			
Chief Officer	Business Director/Deputy Chief Officer/SIRO	Director of Clinical Excellence and Delivery/ Caldicott Guardian	Head of Communications
Director of Human Resources	Associate Director of Clinical Excellence and Quality	Head of Patient Experience and Engagement	Medical Director
Director of Finance	Associate Director Adult Services	Head of Risk/Risk Managers	Head of Quality
Associate Director Primary Care and Specialist Services	Associate Director Child and Family services	Associate Director Mental Health Services	
Additional Circulation			
Specialist – Identified at Strategy Meeting	Relevant Head of Service– Identified at Strategy Meeting	The Lead investigator– Identified at Strategy Meeting	

Appendix 8 – Equality Impact Assessment

To be undertaken and added